PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

as are required to respond to a collection of information unless it contains a valid OMB control number. Under the Paperwork Reduction Act of 1995, no pe

Substitute for form 1449/PTO SEP 1 7 2004

Sheet 1

INFORMATION DISCI

(Use as many sheets as necessary)

of

3

Complete if Known **Application Number** 10/635,117 Filing Date 08/06/2003 First Named Inventor Daniel E. Couto Art Unit 1653 **Examiner Name** Mondesi, Robert B GTC-207 **Attomey Docket Number**

Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	''-	Number-Kind Code ^{2 (I known)}				
80~		^{US-} 4,874,516	10-17-1989	NGK Insulators, Ltd		
1		^{US-} 4,888,115	12-19-1989	Cuno, Incorporated		
		^{US-} 5,256,294	10-26-1993	Genentech, Inc.		
		^{US-} 5,490,937	02-13-1996	Genentech, Inc.		
		^{US-} 5,585,466	12-17-1996	United States of Ame		
4		^{US-} 5,948,441	09-07-1999	The Liposome Company		
		US-				
_		US-				
		US-				
		US-			·	
		US-				
		US-				
·		US-			·	
		US-				
		US-				
		US-				
		US-				
	 	US-		i	·	
··	 	US-			`	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages		
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	To	
						<u> </u>	
	ļ					╫╼	
					· ·		
		,					

			<u> </u>
Examiner Signature	RBM .	Date Considered	11-23-04

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known		
000001.0				Application Number	10/635,117	
INF	ORMATION	N DIS	CLOSURE	Filing Date	08/06/2003	
STA	STATEMENT BY APPLICANT			First Named Inventor	Daniel E. Couto	
(Use as many sheets as necessary)				Art Unit	1653	
		6613 92 II	ecossary)	Examiner Name	Mondesi, Robert	
Sheet	2 ,	of	3	Attorney Docket Number	GTC-207	

<u></u>		NON PATENT LITERATURE DOCUMENTS	·		
Examiner Cite No.1					
RP/	Andersson, "The Heterogeneity of Bovine Serum Albumin," BIOCHIM BIOPHYS. ACTA. 117:115-133 (1966)				
<u></u>		Alun, J. et al., Activity Of Microbial Peptidases, Oxidases, And Esterases In Lake Waters Of Varying Trophic Status, CAN J MICROBIOL 39(8):795-803 (1993)			
		Aranha-Creado et al., Cumulative Viral Titer Reduction Demonstrated By Sequential Challenge Of A Tangential Flow Membrane Filtration System And A Direct Flow Pleated Filter Cartridge, PDA J PHARM SCI TECHNOL 51 (5): 208-212 (1997)	_		
·		Aravindan GR, et al., Identification, Isolation, And Characterization Of A 41-Kilodalton Protein From Rat Germ Cell-Conditioned Medium Exhibiting Concentration-Dependent Dual Biological Activities, ENDOCRINOLOGY, 138(8): 3259-68 (1997)			
		Federspiel G, et al., Hybridoma Antibody Production In Vitro In Type II Serum-Free Medium Using Nutridoma-SP Supplements: Comparisons With In Vivo Methods, J IMMUNOL METHODS $145(1\theta 2)$: $213-221 (1991)$			
		Gabler et al., Principles of Tangential Flow Filtration: Applications to Biological Processing, in FILTRATION IN THE PHARMACEUTICAL INDUSTRY, pp. 453-490 (1987)			
		Kahn DW, et al., Purification Of Plasmid DNA By Tangential Flow Filtration, BIOTECHNOL BIOENG. 69(1):101-106 (2000)			
		Kawahara H, et al., High-Density Culture Of FM-3A Cells Using A Bioreactor With An External Tangential-Flow Filtration Device, CYTOTECHNOLOGY 14(1):61-66 (1994)			
		Porter, ed., HANDBOOK OF INDUSTRIAL MEMBRANE TECHNOLOGY, (Noyes Publications, Park Ridge, New Jersey,/1990) pp. 160-176			
*		Prado SM, et al., Development And Validation Study For The Chromatographic Purification Process For Tetanus Anatoxin On Sephacryl S-200 High Resolution, BOLL CHIM FARM, 138(7):364-368 (1999)			

		· · · · · · · · · · · · · · · · · · ·	
Examiner	00 1	Date	22 5
Signature	RSMond	Considered	11-2>-0

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (08-03)
Approved for use through 07/31/2006, OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449/PTO **Application Number** 10/635,117 INFORMATION DISCLOSURE **Filing Date** 08/06/2003 STATEMENT BY APPLICANT **First Named Inventor** Daniel E. Couto Art Unit 1653 (Use as many sheets as necessary) **Examiner Name** Mondesi, Robert **Attorney Docket Number** GTC-207 Sheet 3 3 of

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
SUV	,	Ronco et al., On-Line Filtration Of Dialysate: Structural And Functional Features of An Asymmetric Polysulfone Hollow Fiber Ultrafilter, INT J ARTIF ORGANS 17(10):515-20 (1994)	
200	-	Strauss PR, Use Of Filtron Mini-Ultrasettetm Tangential Flow Device And Filtron Microseptm Centrifugal Concentrators In The Early Stages Of Purification Of DNA Polymerases, BIOTECHNIQUES 18(1): 158–160 (1995)	
	·		
*			
	,		

Examiner	00 11	Date	
Signature	REMO	Considered	11-24-0.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.